

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,

Plaintiffs,

**V.**

**C.A. No. 18-192 (CFC)**

**FRESENIUS KABI USA, LLC and  
FRESENIUS KABI ONCOLOGY LIMITED,**

**Defendants.**

PHARMACYCLICS LLC, and JANSSEN  
BIOTECH, INC.,

**Plaintiffs,**

**v.**

C.A. No. 18-237 (CFC)

**SHILPA MEDICARE LIMITED, SUN  
PHARMA GLOBAL FZE and SUN  
PHARMACEUTICAL INDUSTRIES LTD.,**

**Defendants.**

**PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,**

**Plaintiffs,**

**v.**

**C.A. No. 18-247 (CFC)**

**CIPLA LIMITED and CIPLA USA INC.,**

**Defendants.**

PHARMACYCLICS LLC and JANSSEN	)	
BIOTECH, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 18-275 (CFC)
	)	
ZYDUS WORLDWIDE DMCC, CADILA	)	
HEALTHCARE LIMITED, TEVA	)	
PHARMACEUTICALS USA, INC.,	)	
SANDOZ INC. and LEK	)	
PHARMACEUTICALS D.D.,	)	
	)	
Defendants.	)	
	)	

**PROPOSED PROTECTIVE ORDER**

WHEREAS, the parties have stipulated that certain information, documents and things of the parties subject to pleading, discovery, or disclosure in this Action be treated as confidential;

WHEREAS this Action may involve the discovery and disclosure of certain information, documents, and things in the possession, custody, or control of Plaintiffs Pharmacyclics LLC (“Pharmacyclics”) and Janssen Biotech, Inc. (“Janssen”) (collectively, “Plaintiffs”); and Defendants Fresenius Kabi USA, LLC, Fresenius Kabi Oncology Limited (collectively, “Fresenius Kabi”); Shilpa Medicare Limited (“Shilpa”); Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. (collectively, “Sun”); Cipla Limited, Cipla USA Inc. (collectively, “Cipla”); Zydus Worldwide DMCC, Cadila Healthcare Limited (collectively, “Zydus”); Teva Pharmaceuticals USA, Inc. (“Teva”); and Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, “Sandoz”); (all collectively “Defendants”); or non-parties that constitute or contain trade secrets or other confidential research, development, or commercial information within the meaning of Federal Rule of Civil Procedure 26(c);

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the parties or non-parties and the medical privacy of non-parties; and

WHEREAS the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Federal Rule of Civil Procedure 26(c) for the purpose of advancing the progress of this case and to prevent unnecessary dissemination or disclosure of such confidential information.

IT IS HEREBY ORDERED:

**DEFINITIONS**

1. The term “Confidential Information” shall mean any document or other tangible thing or any electronically stored information or oral testimony designated pursuant to this Protective Order that contains, reveals, or reflects what a party or non-party reasonably considers to be its trade secrets, or other confidential business, proprietary, technical, or commercially sensitive information, information it has maintained in confidence, information that it has an obligation to a third party to keep confidential, or other information required to be kept confidential by law, including without limitation: research and development information; regulatory submissions, correspondence, and communications (to the extent not publicly available); patent applications and prosecution related thereto (to the extent not publicly available); financial, budgeting and/or accounting information; information about existing and potential customers; marketing and other business strategies, decisions, or negotiations; personnel compensation, evaluations, and other employment information; settlement agreements and communications; and information about the health status, provision of health care to, or payment for health care provided to identified or reasonably identifiable individuals. Each party shall act reasonably and in good faith in designating information as “Confidential Information.”

2. The term “Designating Party” refers to the party or non-party that designates information or items that it produces in disclosures or in responses to discovery as Confidential Information.

3. “Discovery Material” means all documents or other tangible things or electronically stored information, testimony, pleadings, exhibits, and all other material or information produced or disclosed, directly or indirectly, in this Action, including without limitation responses to requests for production of documents and/or things, answers to interrogatories, responses to requests for admissions, documents and things produced or made available for inspection, deposition testimony, expert testimony and reports, and all other discovery taken pursuant to the Federal Rules of Civil Procedure, including third party discovery pursuant to Rule 45, matters in evidence and any other information hereafter furnished, directly or indirectly, by or on behalf of any party, third party, or witness in connection with this Action. This Protective Order and protections herein shall apply to all Discovery Material.

4. The term “Receiving Party” refers to the party that receives the Confidential Information of a Designating Party.

5. The term “this Action” refers, collectively, to the actions captioned *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-192 (GMS) (D.Del.); *Pharmacyclics LLC et al. v. Shilpa Medicare Ltd. et al.*, C.A. No. 18-237 (GMS) (D.Del.); *Pharmacyclics LLC et al. v. Cipla Ltd. et al.*, C.A. No. 18-247 (GMS) (D.Del.); and *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 18-275 (GMS) (D.Del.).

#### **USE OF CONFIDENTIAL INFORMATION**

6. Documents or information designated as Confidential Information shall be disclosed only to:

- a. The Court before which this Action is pending and its official personnel;

b. The following Plaintiffs' Outside Counsel retained for this Action and their law firms' active members, attorneys, law clerks, paralegals, office staff, and employees working on this Action or whose duties or responsibilities require access to Confidential Information designated under this Protective Order ("Plaintiffs' Outside Counsel"):

- i. Covington & Burling LLP
- ii. Patterson Belknap Webb & Tyler LLP
- iii. Morris, Nichols, Arsht & Tunnell LLP

c. The following Defendants' Outside Counsel retained for this Action and their law firms' active members, attorneys, law clerks, paralegals, office staff, and employees working on this Action or whose duties or responsibilities require access to Confidential Information under this Protective Order ("Defendants' Outside Counsel"):

- i. Farnan LLP
- ii. Schiff Hardin LLP
- iii. Smith, Katzenstein & Jenkins LLP
- iv. Sughrue Mion, PLLC
- v. Richards, Layton, & Finger, P.A.
- vi. Calson, Caspers, Vandenburg, Lindquist & Schuman, P.A.
- vii. Phillips, Goldman, McLaughlin & Hall, P.A.
- viii. Goodwin Procter LLP
- ix. Potter Anderson & Corroon LLP
- x. Arent Fox LLP
- xi. Shaw Keller LLP
- xii. Polsinelli PC

xiii. Heyman Enerio Gattuso & Hirzel LLP

xiv. Alston & Bird LLP

d. Up to three (3) in-house attorneys (“Attorney Designees”), as well as paralegal assistants, stenographic and clerical employees working under the supervision of the Designees, for each of Pharmacyclics, Janssen, Fresenius Kabi, Shilpa, Sun, Cipla, Zydus, Teva and Sandoz, provided that such in-house attorneys are identified in writing to counsel for Defendants or Plaintiffs as the case may be at least seven (7) days prior to the disclosure of any Confidential Information to such in-house attorneys (unless the parties agree to waive or lessen the waiting period in writing).

e. However, for the duration of this Action and a period extending one year from the end of this Action, including appeals, any Outside Counsel, Attorney Designee, or In-House Designee receiving Confidential Information pursuant to Paragraphs 6(b), (c), (d), or (f) is expressly prohibited from participating formally or informally in (i) the prosecution of patent applications relating to ibrutinib before the United States Patent and Trademark Office or any corresponding foreign patent authority, including participating in any drafting or amendment of claims in any *inter partes* review, post grant review, or reissue or reexamination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board; and (ii) the preparation or submission of any United States Food and Drug Administration (“FDA”) documents and/or correspondence (including citizen petitions) or any similar documents in any foreign country, regarding approval requirements for any product containing ibrutinib, except to the extent such correspondence solely relates to the Receiving Party’s own application. But, nothing in this paragraph shall otherwise prevent an Outside Counsel or Designee who receives Confidential Information from working on, participating in directly or indirectly, or having

primary responsibility for (a) any *inter partes* review, post grant review, or reissue or reexamination proceeding at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board related to ibrutinib, or (b) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to ibrutinib, so long as such person does not participate in the drafting or amendment of claims during such proceedings.

f. In lieu of the in-house attorney access provided for in Paragraph 6(d), and only to the extent that Zydus does not employ any in-house attorneys who have oversight of this Action, Zydus may designate one (1) in-house employee (“Zydus’s In-House Designee”), as well as assistants, stenographic and clerical employees working under the supervision of Zydus’s In-House Designee to receive Confidential Information under this Protective Order, to the extent that and so long as that person is directly responsible for overseeing and managing the Action and litigation management or support is one of his/her normal duties. However, for the duration of this Action and a period extending one year from the end of this Action, including appeals, Zydus’s In-House Designee receiving Confidential Information pursuant to this Paragraph, is expressly prohibited from participating formally or informally in any of the activities set forth in Paragraph 6(e). If Zydus desires to disclose Confidential Information to an In-House Designee, it shall first obtain a signed declaration in the form shown in attached Exhibit B. At least seven (7) days in advance of the first proposed disclosure of any Confidential Information to the In-House Designee, Zydus shall serve on counsel for Plaintiffs by electronic mail the signed declaration in the form shown in attached Exhibit B along with the proposed In-House Designee’s name, business address, and title. Any objection to disclosing Confidential Information to the In-House Designee must be made in writing and served upon Zydus within seven (7) days after receiving the signed declaration. If there is no such objection within the allotted seven (7) day time period,

the In-House Designee shall thereafter be qualified to receive Confidential Information. In the event Plaintiffs makes a timely objection, it must also seek relief from the Court within seven (7) days from the date they made their written objection (or within such time as agreed between the parties).

g. A party may, as necessary when an Attorney Designee identified by that party changes positions or leaves that party's employment, and on a one-for-one basis, identify a substitute Attorney Designee meeting the criteria above, provided that the party provides the opposing parties seven (7) days written notice prior to said substitution (unless the parties agree to waive or lessen the waiting period in writing). Zydus may, as necessary if its identified In-House Designee changes positions or leaves Zydus's employment, and on a one-for-one basis, identify a substitute In-House Designee meeting the criteria above, provided that Zydus shall first obtain a signed declaration in the form shown in attached Exhibit B. At least seven (7) days in advance of the first proposed disclosure of any Confidential Information to the In-House Designee, Zydus shall serve on counsel for Plaintiffs by electronic mail the signed declaration in the form shown in attached Exhibit B along with the proposed substitute In-House Designee's name, business address, and title. Any objection to disclosing Confidential Information to the In-House Designee must be made in writing and served upon Zydus within seven (7) days after receiving the signed declaration. If there is no such objection within the allotted seven (7) day time period, the In-House Designee shall thereafter be qualified to receive Confidential Information. In the event Plaintiffs makes a timely objection, it must also seek relief from the Court within seven (7) days from the date they made their written objection (or within such time as agreed between the parties). A party may also as necessary substitute Outside Counsel meeting the criteria above, provide that the party provides the opposing parties seven (7) days



written notice prior to said substitution (unless the parties agree to waive or lessen the waiting period in writing). The restrictions of this Protective Order, including the restrictions listed in Paragraph 6(e), continue to apply to any person who is, or was at any time, designated under Paragraphs 6(b), (c), (d), (f), or (g).

h. Court reporters, stenographers, videographers, interpreters, translators, third-party photocopy, data or imaging services contractors, third-party contractors producing graphic or visual aids, courtroom technicians, trial consultants, jury consultants, mock jurors, and other vendors and their respective assistants retained for the purpose of providing litigation support services to Plaintiffs' Outside Counsel or Defendants' Outside Counsel in the Action;

i. Subject to Paragraph 16, any independent expert or consultant (along with their staff and other individuals working on the Action at their direction or under their supervision whose duties or responsibilities require access to Confidential Information under this Protective Order) who is retained by any of Plaintiffs' Outside Counsel or any of Defendants' Outside Counsel for the purpose of assisting in the Action; and

j. Any other person who is permitted to receive Confidential Information by order of the Court or by written agreement of the parties.

7. The protections conferred by this Protective Order cover not only Confidential Information (as defined above), but also (1) any information copied or extracted from Confidential Information; (2) all copies, excerpts, summaries, or compilations of Confidential Information; (3) any testimony, conversations, or presentations by the parties or their respective counsel that might reveal Confidential Information; and (4) any tests, reports, analyses or other information that may be derived from Confidential Information.

8. Confidential Information shall be disclosed only to those persons listed in Paragraph 6, with the exception that Plaintiffs may only disclose, summarize, describe, reveal, or otherwise make available in whole or in part any Confidential Information produced by one Defendant to representatives of another Defendant identified in Paragraphs 6(c) and 6(i), to individuals identified in Paragraph 6(h), or as otherwise agreed to by the Designating Defendant. Confidential Information shall be used solely for the purpose of this Action and any appeal of this Action. Confidential Information shall not be used or disclosed by a person listed in Paragraph 6 for any other purposes. This Protective Order places no limitation on a Designating Party's use or disclosure of its own Confidential Information.

9. Nothing in this Protective Order shall prevent any person, including persons listed under Paragraph 6, from making use of any information that is designated as Confidential Information if such information:

- a. Was lawfully in his or her possession prior to receipt under the provisions of this Protective Order, and is not subject to any other applicable confidentiality agreement;
- b. Was or becomes available to the public through no fault of said person;
- c. Was or is obtained from a source not under an obligation of secrecy to the Designating Party;
- d. Is exempted from the operation of this Protective Order by written consent of the Designating Party; or
- e. Is exempted from the operation of this Protective Order by order of this Court.

**DISCLOSURE OF CONFIDENTIAL INFORMATION**

10. Confidential Information shall not be made available to anyone other than a person to whom disclosure is permitted under Paragraphs 6 and 8, above, or the Designating Party, except as otherwise provided in this Protective Order.

11. A document that contains or reveals Confidential Information may be shown to any witness testifying under oath if the witness is indicated in such document to be its originator or author or recipient of a copy, or if by laying a foundation during the examination, it is established that there was a reasonable possibility that the witness had previously seen such document or was privy to the Confidential Information reflected therein.

12. Confidential Information may be disclosed to a witness testifying under oath if the witness is an officer, director or employee of the Designating Party or is testifying for the Designating Party pursuant to Federal Rule of Civil Procedure 30(b)(6).

13. Confidential Information may be disclosed to a witness testifying under oath if the witness was formerly an officer, director or employee of the Designating Party and the Confidential Information was in existence during the period of his or her service or employment.

14. Confidential Information may be disclosed to a witness testifying under oath if, subject to Paragraph 8, the witness is authorized to access Confidential Information pursuant to Paragraph 6 of the Protective Order.

15. Nothing in this Protective Order shall prevent disclosure of Confidential Information if the Designating Party consents in writing to such disclosure or if this Court orders such disclosure.

16. Counsel desiring to disclose Confidential Information to an independent expert or consultant according to Paragraph 6(i) shall first obtain a signed declaration in the form shown in attached **Exhibit A** from that person. At least seven (7) days in advance of the first proposed

disclosure of any Confidential Information to that person, counsel shall serve on all parties by electronic mail that person's signed declaration in the form shown in attached **Exhibit A** and curriculum vitae or equivalent resume disclosing the individual's employment history and all cases in which the individual has testified in a deposition or a trial in the past four years. Any objection to disclosing Confidential Information to the expert or consultant must be made in writing and served upon each other party within seven (7) days after receiving the signed declaration. If there is no such objection within the allotted seven (7) day time period, the witness or consultant shall thereafter be qualified to receive Confidential Information. In the event a Designating Party makes a timely objection, it must also seek relief from the Court within seven (7) days from the date it made its written objection (or within such time as agreed between the Designating and Receiving Parties); otherwise such objection shall be deemed to be withdrawn and the expert or consultant shall thereafter be qualified to receive Confidential Information. The objecting party shall have the burden of proving that disclosure should not be made. If a Designating Party timely objects to the proposed disclosure and such objection is not withdrawn, the Designating Party's Confidential Information shall not be disclosed to the identified expert or consultant until the objection has been resolved by the Court or by the parties.

17. Defendants' Attorney Designees and In-House Designees identified in Paragraphs 6(d) and 6(f) shall not have access to any document or electronic database containing another Defendant's Confidential Information.

18. As necessary, the parties shall propose to the Court procedures for handling Confidential Information at hearings and trial.

**IDENTIFICATION AND MARKING OF CONFIDENTIAL INFORMATION**

19. Any party may designate Discovery Material it produces in this Action as CONFIDENTIAL in accordance with this Protective Order if such party reasonably and in good faith believes that such Discovery Material contains Confidential Information as defined in Paragraph 1.

20. Any document or other tangible thing that contains or reveals Confidential Information shall be labeled with the legend "CONFIDENTIAL." For a document, such marking shall appear on each page of the document that contains Confidential Information, provided that the requirement to mark each page shall not apply where documents are produced in native form (unless reasonably practical) or were produced in prior litigation and were marked in some other manner to indicate their confidential status. Documents produced prior to the entry of the Protective Order and labeled as being produced or provided pursuant to Local Rule 26.2 shall be treated as if designated CONFIDENTIAL pursuant to this Protective Order. Any Confidential Information not reduced to documentary or physical form or which cannot be conveniently labeled shall be so designated by the Designating Party by serving written notice on all parties. Any document or other tangible thing so labeled and the information it contains or reveals shall be treated in accordance with the provisions of this Protective Order.

21. When a party initially produces documents for inspection, no marking need be made by the Designating Party in advance of the inspection. There will be no waiver of confidentiality, or any privilege or immunity, by the inspection of Confidential Information before it is copied and marked confidential pursuant to the procedure of this Protective Order. For purposes of the inspection, all documents shall be treated as Confidential. After the inspecting party selects documents for production, the Designating Party shall appropriately mark the copies of the selected documents before they are provided to the Receiving Party.

22. Documents and things produced or made available for inspection may be subject to redaction, in good faith by the Designating Party, of information that is subject to the attorney-client privilege, to work-product immunity, or any other applicable privilege or immunity; to applicable personal or data privacy protection laws or regulations; or to commercially sensitive information about products that are unrelated to this Action. This Paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information.

23. Information disclosed at the deposition of a party or one of its present or former officers, directors, employees, or agents may be designated as Confidential Information by that party either (a) on the record at the deposition or (b) by serving a written notification on each Receiving Party within twenty-one (21) days of receipt of the final transcript by counsel for the Designating Party. All information disclosed during a deposition shall be treated as Confidential until at least twenty-one (21) days after the final transcript of the deposition is received by or made available to counsel for each of the parties. Deposition transcripts containing Confidential Information shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER," or similar language. The use of a document as an exhibit at a deposition shall not in any way affect its designation as "CONFIDENTIAL."

24. Subject to Paragraphs 8 and 16, only persons listed in Paragraph 6 and the deponent shall be allowed to attend any portion of a deposition in which Confidential Information is used or elicited from the deponent, unless the Designating Party for such Confidential Information agrees otherwise.

#### **INADVERTENT FAILURE TO DESIGNATE**

25. The inadvertent failure by a party to designate specific documents or materials as containing Confidential Information shall not be deemed a waiver in whole or in part of a claim

of confidentiality as to such documents or materials. Once the Receiving Party has been informed of the failure to designate pursuant to this Paragraph, the Receiving Party shall take reasonable steps to, at the Designating Party's option, either ensure that all copies of any such Discovery Materials are returned promptly to the Designating Party for proper designation or ensure that all copies of any such Discovery Materials are marked with the proper designation and distributed only as permitted under this Protective Order.

**UNAUTHORIZED DISCLOSURE OF CONFIDENTIAL INFORMATION**

26. If a Receiving Party learns that, by inadvertence or otherwise, it has disclosed Confidential Information to any person or in any circumstance not authorized under this Stipulated Protective Order, the Receiving Party must immediately (a) notify in writing the Designating Party of the unauthorized disclosures, (b) and use its best efforts to retrieve all unauthorized copies of the Confidential Information, including requesting that the person or persons to whom unauthorized disclosures were made destroy or return all unauthorized copies of the Confidential Information. Nothing here shall prevent the Designating Party whose Confidential Information or material was improperly disclosed from seeking other remedies from the Receiving Party, including damages or injunctive relief.

**CHALLENGES TO CONFIDENTIAL INFORMATION DESIGNATION**

27. If any party disputes or challenges the designation of any information as Confidential Information, such information shall nevertheless be treated as Confidential Information in accordance with the provisions of this Protective Order until such designation is removed by order of the Court or by written consent of the Designating Party.

28. Timing of Challenges. Any Party may challenge a designation of confidentiality at any time. Unless a prompt challenge to a Designating Party's confidentiality designation is necessary to avoid foreseeable, substantial unfairness, unnecessary economic burdens, or a

significant disruption or delay of the litigation, a Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed.

29. Meet and Confer. The party challenging the designation of confidentiality (“Challenging Party”) shall initiate the dispute resolution process by providing written notice of each designation it is challenging and describing the basis for each challenge. The parties shall attempt to resolve each challenge in good faith and must meet-and-confer within fourteen (14) days of the date of service of notice. In conferring, the Challenging Party must explain the basis for its belief that the confidentiality designation was not proper and must give the Designating Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain the basis for the chosen designation. A Challenging Party may proceed to the next stage of the challenge process only if it has engaged in this meet-and-confer process first or establishes that the Designating Party is unwilling to participate in the meet-and-confer process in a timely manner.

30. Judicial Intervention. If the parties cannot resolve a challenge without court intervention, the Challenging Party shall contact the Court in compliance with the Court’s rules within fourteen (14) days of the meet-and-confer. Failure by the Challenging Party to contact the Court within fourteen (14) days of the meet-and-confer shall automatically waive the challenge to the designation. The burden to establish that the information in question should be treated as Confidential Information under this Protective Order lies with the Designating Party.

31. All parties shall continue to treat the material in question as Confidential Information until the Court rules on the challenge.



**INADVERTENT PRODUCTION OF PRIVILEGED INFORMATION**

32. Inadvertent production of materials or documents subject to the attorney-client privilege, work-product immunity or any other applicable privilege or immunity shall be handled as follows, without prejudice to the right of any party to apply to the Court for further protection or disclosure relating to discovery. Inadvertent production of materials or documents subject to the attorney-client privilege, work-product immunity, or any other applicable privilege or immunity itself shall not constitute a waiver of such privilege(s), either as to the inadvertently produced document(s) or information or as to the subject matter disclosed therein.

a. Within seven (7) days of discovering that information produced in discovery should have been withheld on the basis of privilege or immunity, the party that inadvertently produced the information ("Producing Party") shall notify the Receiving Party in writing, identifying the documents or information in question (by Bates number or other identifier), the privilege or immunity invoked and the basis therefor. For clarity, the Producing Party may provide such notice even if the discovery that such information should have been withheld occurs during or after initial use of such information at a hearing or deposition. No demonstration or proof of error, inadvertence, excusable neglect, or absence of negligence shall be required of the Producing Party in order for such party to avail itself of the provisions of this Paragraph. Failure to provide notice of inadvertent disclosure within the seven (7) day period shall not be construed as a general waiver of any applicable privilege(s) with respect to the subject matter disclosed.

b. Upon receiving such notice, the Receiving Party shall within seven (7) days return or destroy the materials or documents and all copies thereof and certify to the Producing Party that all copies thereof have been returned or destroyed, regardless of whether the Receiving Party has an objection to the basis of the privilege(s) asserted, except that the

Receiving Party may retain one copy of the document to rely on in raising the issue with the Court. The parties agree that destroying a document pursuant to this Paragraph does not waive or otherwise alter the right of a party to object to the basis of the privilege(s) asserted.

c. If the Receiving Party believes it has a good-faith basis for challenging the privilege claim, Outside Counsel for the Receiving Party shall provide to Outside Counsel for the Producing Party, within seven (7) days after receipt of the Producing Party's request for return and privilege log, a written explanation of the good-faith basis for its belief that the inadvertently produced materials or documents are not privileged.

d. Should a dispute arise with respect to the inadvertent production, either side may move the Court for a resolution of such dispute in accordance with the discovery matters procedures set forth in the Scheduling Order in this case.

e. For purposes of this Paragraph, the term "inadvertent" shall have the same meaning as the term has in Federal Rule of Evidence 502(b).

**INADVERTENT PRODUCTION OR DISCLOSURE  
OF NON-PRIVILEGED INFORMATION**

33. If any non-privileged information produced during the course of this action is inadvertently produced by the producing party or any agent or vendor of the producing party, such production will not be deemed a waiver as to any relevance objections to its production.

**FILING OF CONFIDENTIAL INFORMATION**

34. All Confidential Information shall, unless otherwise ordered by the Court, be filed in this Action under seal in accordance with the terms and procedures set forth in the Local Rules of the District of Delaware, the Federal Rules of Civil Procedure, CM/ECF Procedures, or applicable appellate rules as appropriate.

35. If necessary, the parties shall propose to the Court procedures for handling Confidential Information at any hearing and/or trial.

**REQUESTS RECEIVED FROM THIRD PARTIES**

36. In the event that any Confidential Information in the possession, custody, or control of any Receiving Party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the Receiving Party to whom the process or discovery request is directed shall: (1) apprise the person or entity seeking such Confidential Information by subpoena or other legal process of this Protective Order; (2) give written notice of such process or discovery request, together with a copy thereof, to Outside Counsel for the Designating Party, request an agreement to make the requested disclosure, and provide the Designating Party with an opportunity to object; and (3) take reasonable steps as permitted by law to prevent the production of Confidential Information until such time that the parties reach an agreement to make the requested disclosure, or the Designating Party moves the Court for an order that the disclosure not be made and the Court resolves the motion. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential Information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

**ADVICE TO CLIENTS**

37. Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to this Action and, in the course thereof, referring to or relying upon his or her examination of Confidential Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose

any Confidential Information if such disclosure would be contrary to the provisions of this Protective Order.

**MISCELLANEOUS**

38. All deadlines set forth in this Order shall be calculated pursuant to Federal Rule of Civil Procedure 6 unless otherwise indicated.

39. Nothing in this Protective Order shall prejudice the right of any party to object to production of any information for lack of relevance, privilege, or any ground other than confidentiality.

40. Nothing in this Protective Order shall prejudice the right of any party to seek at any time a further order modifying this Protective Order. This Protective Order may be modified or amended either by agreement of the parties or by order of the Court.

41. In the event that a new party is added, substituted or brought in, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

42. The terms of this Protective Order may be applied to the documents, information, and things received by a party from any person who is not a party to this Action at the election of such person, provided that the non-party so designates such documents, information, and things. Nothing in this Protective Order shall prohibit a non-party from conferring with the parties to this Action regarding the implementation of more restrictive disclosure and/or use requirements for such non-party's information.

43. Nothing in this Protective Order shall prejudice the right of any party or third party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Confidential Information. Nevertheless,

no information may be withheld from discovery on the ground that the material to be disclosed requires protection greater than that afforded by this Protective Order unless the party claiming a need for greater protection moves for an order providing such special protection pursuant to Federal Rule of Civil Procedure 26(c).

44. For clarity, nothing in this Protective Order shall affect the right of a Designating Party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information, including the right of one Defendant to disclose its own information to another Defendant, or one Plaintiff to disclose its own information to another Plaintiff. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the Designating Party the information becomes public knowledge. Similarly, the Protective Order shall not preclude a Designating Party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by a Receiving Party.

45. By entering this Order and limiting the disclosure of information in this Action, the Court does not intend to preclude another court from finding such information relevant and subject to disclosure in another case. Any person or party subject to this Order who in other proceedings becomes subject to a motion to disclose another party's information designated "CONFIDENTIAL" pursuant to this Protective Order shall promptly notify that party of the motion so that party may have an opportunity to appear and be heard in the other proceeding.

46. The terms of this Protective Order shall supersede and replace the terms, procedures, restrictions, or obligations agreed to in any Offer of Confidential Access executed by the parties prior to the filing of the above-captioned cases. Any documents or information

produced pursuant to any such Offers of Confidential Access shall be treated as Confidential Information pursuant to the terms of this Protective Order.

47. The provisions of this Protective Order shall survive and remain in full force and effect after the termination of this litigation, including any appeals, and this Court will retain jurisdiction for enforcement of this Protective Order and the resolution of any dispute relating thereto.

48. Within ninety (90) days after the termination of this Action, including any appeals and petitions for review, each document and each other tangible thing that contains or reveals Confidential Information and any copies, abstracts, summaries, notes, or other records regarding the contents of any Confidential Information shall be either (a) returned to the attorney of record for the Designating Party or (b) destroyed with a written representation of such destruction being made to the attorney of record for the Designating Party. Notwithstanding the foregoing, Outside Counsel, Attorney Designees, and Zydus's In-House Designee may maintain each of the following: each paper filed with the Court together with any exhibits thereto, each deposition transcript together with the exhibits marked at the deposition, each expert report together with any exhibits thereto, all written discovery and responses thereto, each demonstrative used at trial or any other hearing, each trial or hearing transcript, each exhibit used at trial, each item of correspondence, and all drafts, memoranda, and other documents constituting work product which were based upon or which include Confidential Information. In the event that Outside Counsel, Attorney Designees, or Zydus's In-House Designee maintains such documents, they shall not disclose material containing any Confidential Information to another party or third party absent subpoena or court order. Outside Counsel, Attorney Designees, and Zydus's In-House Designee likewise need not purge their email, document management systems, or back-up tapes,

provided, however, that any Confidential Information contained in such documents retained by counsel shall remain subject to the protections of this Protective Order. No person or Receiving Party is obligated to return or destroy Confidential Information contained on electronic backup, back-up tapes or other archival media, which should be treated in accordance with existing retention policies.

49. The Clerk of the Court may return to counsel for the parties, or destroy, any sealed material at the end of the litigation, including any appeals.

50. Notice of this Protective Order shall be to the parties through their counsel of record in this Action all at their respective addresses of record filed with this Court for this civil Action.

51. In the event anyone shall violate or threaten to violate the terms of this Protective Order, the aggrieved party immediately may apply to obtain injunctive relief against any such person violating or threatening to violate any of the terms of the Protective Order in this Court, and in the event that the aggrieved party does so, the responding party, subject to the provisions of the Protective Order, shall not employ as a defense thereto the claim that the aggrieved party possesses an adequate remedy at law. Any action to enforce this Protective Order, whether to obtain the injunctive relief provide by this Paragraph or otherwise, shall be brought in this Court.

52. All parties shall be bound by the terms of the Protective Order once submitted to the Court.

SO ORDERED this 29<sup>th</sup> day of October, 2018.

  
UNITED STATES DISTRICT JUDGE

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)  
Jeremy A. Tigan (#5239)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@mnat.com  
jtigan@mnat.com

*Attorneys for Pharmacyclics LLC  
and Janssen Biotech, Inc.*

OF COUNSEL:

Christopher N. Sipes  
Erica N. Andersen  
Brienne Bharkhda  
Nicholas L. Evoy  
COVINGTON & BURLING LLP  
One CityCenter  
850 Tenth Street NW  
Washington, DC 20001-4956  
(202) 662-6000

*Attorneys for Pharmacyclics LLC*

Gregory L. Diskant  
Irena Royzman  
Jordan M. Engelhardt  
Lachlan Campbell-Verduyn  
Nicole A. Conlon  
PATTERSON BELKNAP WEBB & TYLER LLP  
1133 Avenue of the Americas  
New York, NY 10036  
(212) 336-2000

*Attorneys for Janssen Biotech, Inc.*



FARNAN LLP

/s/ Brian E. Farnan

Brian E. Farnan (#4089)  
Michael J. Farnan (#5165)  
919 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 777-0300  
bfarnan@farnanlaw.com  
mfarnan@farnanlaw.com

*Attorneys for Fresenius Kabi USA, LLC  
and Fresenius Kabi Oncology Limited*

OF COUNSEL:

Imron Aly  
Keven M. Nelson  
Thomas Rammer  
Tara Kurtis  
SCHIFF HARDIN LLP  
233 South Wacker Drive  
Chicago, IL 60606  
(312) 258-5500

John K. Hsu  
SCHIFF HARDIN LLP  
901 K Street NW, Suite 700  
Washington, DC 20001  
(202) 778-6400

Ahmed M.T. Riaz  
SCHIFF HARDIN LLP  
666 Fifth Avenue, Suite 1700  
New York, NY 10103  
(212) 753-5000

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Eve H. Ormerod

Neal C. Belgam (#2721)  
Eve H. Ormerod (#5369)  
1000 West Street, Suite 1501  
Wilmington, DE 19801  
(302) 652-8400  
nbelgam@skjlaw.com  
eormerod@skjlaw.com

*Attorneys for Shilpa Medicare Limited*

OF COUNSEL:

Chidambaram S. Iyer  
SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, NW,  
Washington, DC 20037  
(202) 775-7542

RICHARDS, LAYTON & FINGER, PA

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)  
Sara M. Metzler (#6509)  
One Rodney Square, Suite 600  
920 North King Street  
Wilmington, DE 19801  
(302) 651-7705  
farnan@rlf.com  
metzler@rlf.com

OF COUNSEL:

Samuel T. Lockner  
Shelleaha L. Jonas  
Todd S. Werner  
Caroline L. Marsili  
CARLSON, CASPERS, VANDENBURGH,  
LINDQUIST & SCHUMAN  
225 South Sixth Street, Suite 4200  
Minneapolis, MN 55402  
(612) 436-9600

*Attorneys for Sun Pharma Global FZE  
and Sun Pharmaceutical Industries Ltd.*

PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)  
David A. Bilson (#4986)  
1200 North Broom Street  
Wilmington, DE 19806  
(302) 655-4200  
jcp@pgmhlaw.com  
dab@pgmhlaw.com

OF COUNSEL:

Elizabeth J. Holland  
Keith A. Zullo  
Steven J. Bernstein  
GOODWIN PROCTER LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
(212) 813-8800

*Attorneys for Cipla Limited and Cipla USA Inc.*

Anjali Moorthy  
GOODWIN PROCTER LLP  
Three Embarcadero Center  
San Francisco, CA 94111  
(415) 733-6000

SHAW KELLER LLP

/s/ Nathan R. Hoeschen

---

John W. Shaw (#3362)  
Karen E. Keller (#4489)  
Nathan R. Hoeschen (#6232)  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
nhoeschen@shawkeller.com

*Attorneys for Teva Pharmaceuticals USA, Inc.*

OF COUNSEL:

Gary E. Hood  
Luke T. Shannon  
Mark T. Deming  
Helena Berezowskyj  
POLSINELLI PC  
150 North Riverside Plaza, Suite 3000  
Chicago, IL 60606  
(312) 819-1900

Rhiannon I. D'Agostin  
POLSINELLI PC  
1401 Lawrence Street, Suite 2300  
Denver, CO 80202  
(303) 572-9300

POTTER ANDERSON & CORROON LLP

/s/ Bindu A. Palapura

---

David E. Moore (#3983)  
Bindu A. Palapura (#5370)  
Stephanie E. O'Byrne (#4446)  
Hercules Plaza, 6th Floor  
1313 North Market Street  
Wilmington, DE 19801  
(302) 984-6000  
dmoore@potteranderson.com  
bpalapura@potteranderson.com  
sobyrne@potteranderson.com

*Attorneys for Zydus Worldwide DMCC  
and Cadila Healthcare Limited*

OF COUNSEL:

Jay R. Deshmukh  
Hershy Stern  
KASOWITZ BENSON TORRES LLP  
1633 Broadway  
New York, NY 10019  
(212) 506-1700

HEYMAN ENERIO GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)  
300 Delaware Avenue, Suite 200  
Wilmington, DE 19801  
(302) 472-7300  
dgattuso@hegh.law

OF COUNSEL:

Natalie C. Clayton  
ALSTON & BIRD LLP  
90 Park Avenue  
New York, NY 10016  
(212) 210-9400

*Attorneys for Sandoz Inc. and  
Lek Pharmaceuticals d.d.*

Shri Abhyankar  
ALSTON & BIRD LLP  
One Atlantic Center  
1201 West Peachtree Street, Suite 4900  
Atlanta, GA 30309-3424  
(404) 881-7687

October 26, 2018  
12315586

**EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

**PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,**

Plaintiffs,

**v.**

C.A. No. 18-192 (CFC)

**FRESENIUS KABI USA, LLC and  
FRESENIUS KABI ONCOLOGY LIMITED,**

**Defendants.**

**PHARMACYCLICS LLC, and JANSSEN  
BIOTECH, INC.,**

**Plaintiffs,**

**v.**

C.A. No. 18-237 (CFC)

**SHILPA MEDICARE LIMITED, SUN  
PHARMA GLOBAL FZE and SUN  
PHARMACEUTICAL INDUSTRIES LTD.,**

**Defendants.**

PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,

**Plaintiffs,**

**v.**

**C.A. No. 18-247 (CFC)**

**CIPLA LIMITED and CIPLA USA INC.,**

**Defendants.**

PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC, CADILA  
HEALTHCARE LIMITED, TEVA  
PHARMACEUTICALS USA, INC.,  
SANDOZ INC. and LEK  
PHARMACEUTICALS D.D.,

Defendants.

C.A. No. 18-275 (CFC)

**AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

I, \_\_\_\_\_, hereby acknowledge that I received a copy of the Protective Order in the above-captioned Action. I have read and understood the Protective Order and agree to be bound by its provisions. I agree not to copy or use any information designated as Confidential Information that may be provided to me for any purpose other than in connection with this Action, and I agree not to reveal any such information to any person not authorized by this Protective Order.

I further acknowledge and understand that a violation of this Protective Order may subject me to penalties of the Court, and I hereby submit to the jurisdiction of the United States District Court for the District of Delaware in connection with any proceedings concerning enforcement of this Protective Order.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Present Employer or Other Business Affiliation

**Defendants.**

PHARMACYCLICS LLC and JANSSEN  
BIOTECH, INC.,

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC, CADILA  
HEALTHCARE LIMITED, TEVA  
PHARMACEUTICALS USA, INC.,  
SANDOZ INC. and LEK  
PHARMACEUTICALS D.D.,

Defendants.

C.A. No. 18-275 (CFC)

**AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

I, \_\_\_\_\_, am employed at \_\_\_\_\_,  
where my current title is \_\_\_\_\_. I hereby acknowledge that I  
received a copy of the Protective Order in the above-captioned Action. I represent that my  
employer does not employ any in-house attorneys who have oversight of this Action and who are  
eligible to be designated under Paragraph 6(d) of the Protective Order. I further represent that I  
am directly responsible for overseeing and managing the Action and litigation management or  
support is one of my normal duties.

I have read and understood the Protective Order and agree to be bound by its provisions. I  
agree not to copy or use any information designated as Confidential Information that may be  
provided to me for any purpose other than in connection with this Action, and I agree not to  
reveal any such information to any person not authorized by this Protective Order.

I further acknowledge and understand that a violation of this Protective Order may  
subject me to penalties of the Court, and I hereby submit to the jurisdiction of the United States  
District Court for the District of Delaware in connection with any proceedings concerning



enforcement of this Protective Order. I further agree to abide by and be subject to the Delaware Code of Professional Conduct.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Business Address